UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

DR. TIMOTHY BAXTER

Plaintiff,

v.

XAVIER BECERRA in his official capacity as SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, and

CHRISTI A. GRIMM, in her official capacity as INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Defendants.

Case No. _____

COMPLAINT

Plaintiff Dr. Timothy Baxter, by and through his attorneys, hereby files his complaint against Defendants Xavier Becerra, Secretary of the United States Department of Health and Human Services, and Christi A. Grimm, Inspector General of the United States Department of Health and Human Services, (collectively, "the Secretary"), alleging as follows:

INTRODUCTION

1. This case concerns whether the Secretary of the Department of Health and Human Services can impose an automatic, career-limiting penalty of exclusion from all federal and state healthcare programs for five years on Dr. Baxter, a doctor with an established record of providing life-saving treatments to patients, based solely on pleading guilty to a single, strict-liability misdemeanor misbranding offense under the "Responsible Corporate Officer" ("RCO") doctrine. That doctrine, which has drawn intense criticism from commentators across the political spectrum, allows the government to charge a corporate officer for a crime committed by a subordinate

without any proof of intent (*mens rea*) or evidence of involvement in the underlying offense. While such strict-liability offenses are themselves strongly disfavored and run counter to our justice system's focus on individual culpability, the Secretary's decision to attach mandatory program exclusion as a civil consequence of such a conviction far exceeds the constitutional and statutory limits on his authority, and, at the very least, raises serious due process concerns.

2. Congress did not intend for the Secretary to have such sweeping authority. At most, Congress allowed the Secretary to *consider* exclusion for an RCO misdemeanor misbranding offense, taking into account all mitigating circumstances that might render such exclusion inappropriate. But in imposing a mandatory exclusion on Dr. Baxter, the Secretary chose instead to ignore the plain text of the statutory exclusion regime Congress enacted.

3. Congress entrusts the Secretary with the responsibility for determining whether an individual may participate in Federal healthcare programs like Medicare and Medicaid. Under Section 1128(a) of the Social Security Act, the Secretary *must* exclude individuals from participating in Federal healthcare programs for a statutory minimum period of five years if they have been convicted of one of four enumerated serious offenses. *See* 42 U.S.C. § 1320a-7(a). By contrast, Section 1128(b) provides that the Secretary *may* exclude individuals if they have been convicted of one of seventeen less serious offenses likewise enumerated in the statute. *See* 42 U.S.C. § 1320a-7(b).

4. Permissive and mandatory exclusion are mutually exclusive categories. A conviction may qualify for mandatory exclusion or permissive exclusion but cannot qualify for both. In contrast to the statutory minimum period of five years for mandatory exclusion, there is no statutory minimum for permissive exclusion and the Secretary often concludes that exclusion is not necessary.

5. Dr. Timothy Baxter is an accomplished physician who has dedicated his career to developing life-changing (and sometimes life-saving) drugs for those who suffer from Opioid Use Disorder, amongst other conditions. In 2020, Dr. Baxter pled guilty to a misdemeanor strict-liability offense under the RCO doctrine after one of his subordinates, unbeknownst to him, shared inaccurate information regarding one such drug. Based on the nature and circumstances of the misdemeanor offense and observing that the Government "doesn't believe" "Dr. Baxter will commit future crimes," the judge sentenced Dr. Baxter to six months' home confinement and expressly permitted him to "leave [his home] to engage in any of the aspects of his employment."

6. Notwithstanding the district court's sentence, the Secretary entered a mandatory exclusion order prohibiting Dr. Baxter from participating in "all Federal health care programs . . . for the minimum statutory period of 5 years." Because the Social Security Act defines "Federal health care program" broadly to include any plan or program that receives at least partial funding from the United States Government, 42 U.S.C. § 1320a–7b(b), the order severely curtails Dr. Baxter's employment opportunities within the medical profession.

7. The Secretary's decision to exclude Dr. Baxter is arbitrary, capricious, violates the Social Security Act, and is unconstitutional. For decades, the Secretary has recognized that convictions for misdemeanor misbranding under the RCO doctrine are subject to permissive exclusion, even where a Medicaid program purchased the misbranded drug. According to the Secretary, that is because a conviction under these circumstances is "a misdemeanor relating to fraud," 42 U.S.C. § 1320a–7(b)(1)(A); *see Friedman v. Sebelius*, 686 F.3d 813, 816 (D.C. Cir. 2012) (upholding permissive exclusion where "executives were convicted under the 'responsible corporate officer' doctrine of the misdemeanor of misbranding a drug" and the facts of the conviction showed "Federal and State health care agencies . . . had been large buyers of the

misbranded drug"), and not "a criminal offense related to the delivery of an item or service under subchapter XVIII," 42 U.S.C. § 1320a–7(a)(1).

8. In Dr. Baxter's case, however, the Secretary reached the opposite conclusion. Jettisoning his prior construction of the Social Security Act, the Secretary held that the statute *mandated* Dr. Baxter's exclusion from all Federal healthcare programs. The Secretary did not acknowledge or explain his new position that RCO misdemeanor misbranding warrants the harsh medicine of mandatory exclusion, nor did he provide anything approaching an adequate justification for his unreasonable construction of the statute and departure from past precedent. Instead, the Secretary erroneously claimed that his exclusion decisions are not subject to Administrative Procedure Act ("APA") standards.

9. Such unreasoned decision-making cannot survive judicial review. Dr. Baxter's misdemeanor conviction cannot qualify for both permissive and mandatory exclusion under the statute. Otherwise, the Secretary would possess virtually limitless discretion either to exclude the physician automatically for five years without any possibility of an exception—as happened here—or to conclude that an RCO misdemeanor misbranding offense is insufficiently serious to warrant any exclusion at all. Such arbitrary discretion, and the disproportionate civil penalties that would automatically attach to an RCO misdemeanor conviction as a result, cannot comport with due process. Because the Social Security Act does not authorize the Secretary to impose a mandatory exclusion on Dr. Baxter, this Court should set aside the agency's decision as contrary to law.

THE PARTIES

10. Plaintiff Dr. Baxter is a medical doctor who has dedicated his life to helping patients—first as a physician in a surgical ward, then as the Global Medical Director at Reckitt Benckiser Pharmaceuticals ("RBP") and Chief Medical Officer of RBP's successor entity,

Indivior, and later as a consultant developing treatments for cocaine overdose, weaponized fentanyl, and breast cancer, among other projects. Dr. Baxter is a citizen of Virginia living in Richmond.

11. Defendant Xavier Becerra is the Secretary of the United States Department of Health and Human Services, which is headquartered in Washington, D.C. As Secretary, he is responsible for administering the Social Security Act, 42 U.S.C. §§ 301, *et seq*., and, in particular, administering both the Medicare Act, 42 U.S.C. §§ 1395, *et seq.*, and the administration of federal responsibilities under the Medicaid Act, 42 U.S.C. §§ 1396, *et seq*. Among these duties, the Secretary of the United States Department of Health and Human Services is tasked with issuing orders of exclusion under 42 U.S.C. § 1320a-7(a)(1).

12. Defendant Christi A. Grimm is the Inspector General of the United States Department of Health and Human Services and serves as the head of the United States Department of Health and Human Services' Office of the Inspector General ("HHS-OIG"). HHS-OIG issues and enforces orders of exclusion under authority delegated by the Secretary of the United States Department of Health and Human Services.

JURISDICTION AND VENUE

13. This Court has subject-matter jurisdiction over this action pursuant to 42 U.S.C. § 1320a-7(f) (incorporating by reference 42 U.S.C. §§ 405(g) and (h)), 5 U.S.C. § 702, and 28 U.S.C. § 1331. The Court has the authority to issue declaratory and other relief under 28 U.S.C. §§ 2201(a) and 2202.

14. This Court has personal jurisdiction over Defendants Xavier Becerra and Christi A. Grimm because they are sued in their official capacity as Secretary of the United States Department of Health and Human Services, and Inspector General of the United States Department of Health and Human Services, respectively.

15. Venue is proper in this Court under 42 U.S.C. § 405(g) because Dr. Baxter resides in the Eastern District of Virginia.

FACTUAL BACKGROUND

A. Dr. Baxter and Indivior

16. Dr. Timothy Baxter is a medical doctor whose vocation is saving and improving lives. He began his career as a physician in a surgical ward. After years of working one-on-one with patients, Dr. Baxter turned his focus toward helping people on a broader scale—working as a pharmaceutical clinical researcher. Until recently, Dr. Baxter worked as a consultant who develops treatments for cocaine overdose, weaponized fentanyl, and women's health issues, among other projects. But for the better part of the past two decades, he worked at Indivior as its chief medical officer.[1]

17. Indivior's biggest impact has been the production of two prescription drugs geared at tackling the opioid crisis and helping persons suffering from opioid use disorder resume their lives. These lifesaving drugs are called Suboxone and Subutex. Both drugs contain buprenorphine, are distributed in tablet form, and are approved by the Food and Drug Administration ("FDA") as Schedule III drugs for the maintenance therapy of opioid addiction in 2002. However, unlike Subutex, Suboxone combines buprenorphine with naloxone and is much less attractive to those who wish to abuse buprenorphine because naloxone precipitates withdrawal symptoms when snorted or injected.

18. In the two decades since Congress approved Suboxone for use outside of a clinical setting, medication-assisted treatment of opioid use disorder has become a critical weapon in the

[1] In December 2014, RBP was demerged from its parent company, Reckitt Benckiser Group, and renamed Indivior. Concurrent with or shortly after the demerger, Dr. Baxter's title changed from Global Medical Director to Chief Medical Officer.

fight against the opioid epidemic. Indeed, prescriptions such as Suboxone have played a crucial role in saving lives from the scourge of drug abuse.

19. Public health officials have praised the benefits of Suboxone, noting that they have "witnessed people with addiction rebuild relationships with family and friends" as a direct result of the drug. Sebastian Tong, et al., *Tong, Melton and Neuhausen column: Why offering medication-assisted treatment is essential to combating Virginia's addiction crisis*, Richmond Times Dispatch (Sept. 5, 2016), https://bit.ly/3pJktfX. They have also seen those suffering from Opioid Use Disorder "start meaningful employment, reduce criminal activity, and obtain steady housing with the aid of these medications." *Id*.

20. In 2010, Indivior brought a new drug to market: a film version of Suboxone which is taken by placing a strip of film under one's tongue where the medication dissolves. Suboxone Film is distributed in unit-dose child-resistant packaging—not bulk pill containers.

21. The Massachusetts Medicaid program ("MassHealth") is "the largest Medicaid program in the country by volume of addiction-treatment-drug business. . . ."

22. By 2011, Suboxone Film and Suboxone Tablet were both available through the MassHealth program, but Suboxone Film was not a preferred drug on the MassHealth program formulary and thus had restrictions on approval for reimbursement.

23. Like other drugs, Suboxone carries a risk to children who take it by accident. When scientifically significant data reflecting the rates of such episodes became available, one of Dr. Baxter's subordinates, Dr. Jane Ruby, shared it with MassHealth.

24. On one occasion in October 2012, Dr. Ruby shared inaccurate data. According to Massachusetts-specific data collected by the Researched Abuse, Diversion, and Addiction-Related Surveillance System ("RADARS"), the rate of unintended pediatric exposures was lower with

Suboxone Film compared to Suboxone Tablet, but the Subutex Tablet risk was lower than both. When sharing this data, however, Dr. Ruby added together the unintended childhood exposure rates for Suboxone Tablets and Subutex Tablets in an apparent (but mistaken) attempt to compare all tablets with Suboxone Film. As a result, the data Dr. Ruby shared suggested that Suboxone Film had the lowest risk, when in fact Subutex Tablets had the lowest overall rate of unintended pediatric exposure.

25. While Dr. Baxter was copied on correspondence containing the raw data collected by RADARS, he was not involved in combining the data or transmitting that data to MassHealth. Indeed, Dr. Ruby informed Dr. Baxter that she planned to obtain combined tablet data from RADARS, and she did not reveal to him that she had made the calculations herself.

26. In November 2012, Dr. Ruby shared a peer-reviewed and published chart depicting accurate and unaltered nation-wide data, also from RADARS, comparing unintended childhood exposures between Suboxone Film and Suboxone Tablets alone. In contrast to the Massachusetts-only data, the national data did not mention Subutex Tablets.[2]

27. In December 2012, the month after Dr. Ruby submitted the chart containing accurate national data, MassHealth issued a prescriber letter stating that MassHealth would adjust its approval criteria with respect to prior authorization requests submitted on behalf of "those [MassHealth] members prescribed Suboxone who live in households with children less than six years of age."

28. As the basis for this expansion of coverage, MassHealth cited the accurate, nationwide published RADARS data "document[ing] a greater unintentional exposure risk of

[2] A subsequently published analysis of national data would later confirm that Suboxone Film did in fact have a lower rate of exposure than both Suboxone Tablets and Subutex Tablets.

buprenorphine/naloxone tablets than with that of the film in children 0 to five years of age." MassHealth did not cite or appear to rely upon the inaccurate data provided by Dr. Ruby.

29. In December 2015, Indivior sent MassHealth a correction letter regarding the misleading pediatric exposure data shared previously.

30. Just one month later—after Indivior flagged Dr. Ruby's inaccurate submission—MassHealth promoted Suboxone Film to be the "preferred buprenorphine/naloxone product" for all MassHealth beneficiaries. After this change, "all other formulations [would] require prior authorization" even though Suboxone Film generally would not.

31. Despite years of investigations that led to Dr. Baxter's misbranding conviction, Suboxone Film remains the preferred buprenorphine/naloxone product for all MassHealth beneficiaries.

B. Government Investigation and Prosecution

32. In prosecuting Dr. Baxter for RCO misdemeanor misbranding, the government proceeded under the theory that the chart depicting accurate information about the national rate of accidental childhood exposures to Suboxone Tablets versus Suboxone Film, which Dr. Ruby shared later, was misleading in light of her prior inaccurate statements about state-level data.

33. Under the heavily criticized RCO doctrine, the government may charge corporate officials in a "position of authority" who fail to prevent or correct a violation of the Food, Drug, and Cosmetic Act ("FDCA"). *See United States v. Park*, 421 U.S. 658 (1975). Those charged under such a theory need not have committed FDCA violations themselves, nor do they even need to have been aware of a subordinate's violation to be prosecuted. *See Meyer v. Holley*, 537 U.S. 280, 287 (2003) (RCO doctrine imposes an "unusually strict rule[]").

34. In this case, the government believed that it could charge Dr. Baxter and other senior Indivior officials with misdemeanor offenses simply because they held positions of

authority over Dr. Ruby (who was never herself charged).

35. Dr. Baxter ultimately pleaded guilty to, and was convicted of, RCO misdemeanor misbranding in violation of the FDCA. Specifically, Dr. Baxter pleaded guilty to violating 21 U.S.C. §§ 33l(a) and 333(a)(l). Section 331(a) prohibits "[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded." Section 333(a)(1) sets the maximum penalty for violating Section 331(a) at one year's imprisonment and a $1,000 fine.

36. Because the RCO doctrine holds an individual strictly liable for his subordinate's conduct, the government never had to prove that Dr. Baxter had any intent concerning, involvement in, or knowledge of, Dr. Ruby's conduct. Nor has Dr. Baxter ever acknowledged that he had any manner of criminal intent, and neither the indictment nor guilty plea suggest otherwise.

37. Because "due process places some limits" on the government's ability to punish individuals for strict liability offenses, *Lambert v. People of the State of California*, 355 U.S. 225, 228 (1957), the criminal sanction Dr. Baxter received was appropriately a modest one. Although part of Dr. Baxter's sentence included six-months' home confinement, the sentencing court ensured that Dr. Baxter would be allowed to "leave to engage in any of the aspects of his employment. . . ." As the court acknowledged, "[t]he government I don't believe thinks that particularly in relation to the particular offense of which Dr. Baxter has pled guilty that Dr. Baxter will commit future crimes."

38. The court with supervision responsibilities proceeded under the same assumption, and authorized Dr. Baxter to travel outside the district "for matters related to his employment or his licensure."

39. Notably, Dr. Baxter was not required to pay any form of restitution—an indication

that Dr. Baxter's misdemeanor offense did not result in loss or harm to a Federal healthcare program.

C. Dr. Baxter's Exclusion

40. Although he had parted ways with Indivior, Dr. Baxter was ready to move forward with his life following his guilty plea. Unfortunately, despite the district court's decision to impose a sentence that would allow Dr. Baxter to continue his important work, the Secretary had other ideas.

41. Pursuant to Section 1128 of the Social Security Act, the Secretary has the authority to exclude people convicted of certain crimes from participating in Federal healthcare programs. Moreover, the statute forces employers to cease employing excluded individuals. *See* 42 U.S.C. 1320a-7a(a)(6). Suffice to say, an exclusion has severe consequences—significantly limiting the number of positions available to a medical provider.

42. The statute imposes mandatory exclusions for four serious categories of convictions. *See* 42 U.S.C. § 1320a–7(a)(1)–(4). For instance, the Secretary *must* exclude "[a]ny individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under" Medicaid, *id*. § 1320a–7(a)(1), and any individual whose conviction is "relat[ed] to neglect or abuse of patients in connection with the delivery of a health care item or service," *id*. § 1320a–7(a)(2).

43. By contrast, the Secretary *may* exclude someone on a permissive basis for any of seventeen less serious convictions. *Id*. § 1320a–7(b)(1)–(17).

44. Under established principles of statutory construction, case law, and common sense, Section 1128(a) and 1128(b) are mutually exclusive. That is to say, if a particular conviction qualifies for *permissive* exclusion under 42 U.S.C. § 1320a–7(b), it cannot logically also qualify for *mandatory* exclusion under 42 U.S.C. § 1320a–7(a).

45. On March 31, 2021, HHS-OIG notified Dr. Baxter that he was subject to *mandatory* exclusion under Section 1128(a).

46. Because that exclusion became effective without giving Dr. Baxter prior notice or an opportunity to be heard, Dr. Baxter filed a complaint in the U.S. District Court for the Eastern District of Virginia challenging the decision as violating his procedural due process rights. Under a settlement agreement with Dr. Baxter, HHS-OIG withdrew the exclusion decision and agreed that Dr. Baxter should be allowed ninety days to respond to any future notice.

47. On May 27, 2021, HHS-OIG issued a new letter, which notified Dr. Baxter that the Secretary intended to exclude him on the basis that his conviction was "a criminal offense related to the delivery of an item or service under" Medicaid, 42 U.S.C. § 1320a-7(a)(1), and therefore *mandated* his exclusion from Federal healthcare programs for five years. Dr. Baxter filed a response on August 30, 2021. On September 30, 2021, HHS-OIG issued a letter informing Dr. Baxter that the agency would indeed impose a mandatory exclusion.

48. Pursuant to the Department's rules, Dr. Baxter appealed his exclusion to an Administrative Law Judge ("ALJ"), and then to the Departmental Appeals Board ("DAB"), each of which affirmed the exclusion.

49. The DAB's opinion—the final decision of the agency—affirmed Dr. Baxter's exclusion despite the fact that the Secretary had previously argued, all the way to the federal court of appeals in D.C., that misbranding cases brought under the RCO doctrine were "misdemeanors . . . relating to fraud" under the *permissive* exclusion provisions of the Act. Despite the fact that such offenses fit textually, if anywhere, as permissive exclusions, the DAB concluded that Dr. Baxter's conviction required mandatory exclusion as a "criminal offense related to the delivery of an item or service" under Medicaid.

50. But where specific textual language requires the Secretary to treat an exclusion as permissive, the Secretary cannot rely on an alternate category of offenses to declare the exclusion mandatory. *See Leddy v. Becerra*, No. 22CV4252GRBLGD, 2022 WL 2978620, at *5–6 (E.D.N.Y. July 28, 2022). Otherwise, the Secretary would possess limitless discretion either to provide physicians an opportunity to argue that no exclusion should be imposed (or only one of short duration) or impose a five-year moratorium on their employment as a matter of law.[3]

51. Indeed, it is highly doubtful that Congress, in drafting Section 1128, intended to allow an RCO misdemeanor misbranding conviction to result in mandatory exclusion. To conclude otherwise—that such a harsh penalty should attach to a strict liability offense—would raise serious due process concerns.

52. Nor did the agency explain why it treated Dr. Baxter's conviction differently than similarly situated cases in the past. Prior to Dr. Baxter's plea, HHS-OIG had never interpreted mandatory exclusion to reach misdemeanor misbranding offenses in the absence of a restitution or forfeiture order showing a nexus between the offense and delivery of an item or service under Medicare and Medicaid—*i.e.*, that the offense was "related to the delivery of an item" for purposes of the statute. *See, e.g.*, *Schmidt*, DAB CR3746, at 9 (2015) ("In exclusion cases, restitution has long been considered a reasonable measure of program loss and evidence of the nexus between the offense and the program to which restitution is to be made.") (citing *Leon*, DAB CR2533, at 5 (2013); *Wilder*, DAB CR2416, at 9 (2011); *Hollady*, DAB CR1855 (2002)); s*ee also, e.g.*, *Parrino*, DAB CR3287 (2014) (restitution of $14,098.24); *Miranda*, DAB CR3755 (2016) (restitution of over $1 million); *Aswad*, DAB CR2741 (2016) (restitution of over $1 million); *Keegan*, DAB

[3] Should Dr. Baxter prevail in this appeal of the Secretary's decision, he reserves all rights to challenge whether permissive exclusion pursuant to Section 1128(b) would be appropriate.

CR3242 (2014) (restitution of over $2 million); *cf. Hoffmeister*, DAB CR3973, at 2–3 (2015) ("*Based on Petitioner's restitution* and the records from his underlying conviction, I find Petitioner's criminal offense and subsequent conviction relate directly to his delivery of podiatry services under Medicare." (emphasis added)).

53. To be sure, Dr. Baxter accepted responsibility for misdemeanor misbranding under the RCO doctrine. But to the best of Dr. Baxter's knowledge at the time of his plea, HHS-OIG never previously held that an individual convicted of an RCO misdemeanor should be subject to mandatory exclusion, and through Dr. Baxter's administrative appeals, the Secretary was unable to present a contrary example. Moreover, the Secretary failed to justify how the agency could impose a mandatory exclusion on Dr. Baxter after having acted pursuant to its permissive authority in imposing exclusions on others convicted of the same RCO misdemeanor offense. Specifically, in *Friedman v. Sebelius*, 686 F.3d 813, 816 (D.C. Cir. 2012), the D.C. Circuit affirmed a permissive exclusion where "[a]ppellants pleaded guilty to misdemeanor misbranding, in violation of 21 U.S.C. § 331(a) and § 333(a)(1) . . . [u]nder the 'responsible corporate officer' doctrine."

54. The facts in *Friedman* were materially indistinguishable from those of Dr. Baxter's case.[4] Plaintiffs' subordinates had misrepresented information, misleading state healthcare agencies into purchasing the drug at issue. *See id.* at 825. While Plaintiffs in that case had pled guilty to misdemeanor misbranding violations under the RCO doctrine, the D.C. Circuit agreed with the Secretary that their offenses qualified as "a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial

[4] If anything, the offense in *Friedman* was significantly more serious. Plaintiffs' subordinates in that case "'with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.'" *Friedman*, 686 F.3d at 816 (quoting *United States v. Purdue Frederick Co.*, 495 F.Supp.2d 569, 571 (W.D.Va.2007)).

misconduct" *id.* at 820 (quoting 42 U.S.C. § 1320a–7(b)(1)), and therefore subjected plaintiffs to permissive exclusion.

55. Yet when it came to Dr. Baxter, HHS-OIG now claimed that the very same conviction, resulting from materially indistinguishable facts, qualified for mandatory exclusion under Section 1128(a)(1). The Secretary's attempts to distinguish Dr. Baxter's case from *Friedman* were unavailing. For example, the Secretary claimed that *Friedman* did not involve "direct representations to a state Medicaid program" and that the delivery of the drug was "without regard to a particular health care program." But the DAB overlooked that the district court in *Friedman* had required plaintiffs' employer to pay restitution to federal and state healthcare agencies. *See Friedman*, 686 F.3d at 816.

56. Other reasoning allegedly supporting the DAB's decision was similarly suspect. Although affirming the ALJ's conclusion that to justify mandatory exclusion the Secretary must establish a "common-sense nexus" between Dr. Baxter's conviction and "the delivery of an item or service under" Medicaid, 42 U.S.C. 1320a–7(a)(1), the DAB's decision ignored or failed to adequately address evidence showing that Dr. Baxter's conviction was unrelated to the delivery of Suboxone Film under MassHealth.

57. The evidence shows MassHealth's decisions were unaffected by the misbranding for which Dr. Baxter was held responsible.

58. Suboxone Film was covered by the MassHealth program prior to the misbranding.

59. The MassHealth order making it easier for certain MassHealth beneficiaries to obtain Suboxone Film cited only accurate, nation-wide data to justify the decision.

60. After Indivior informed MassHealth about the misbranding, MassHealth promoted Suboxone Film to be the preferred product in its category for all MassHealth beneficiaries.

61. Even if MassHealth's decisions were affected by the misbranding, the Secretary presented no evidence showing that these decisions or the misbranding itself had caused MassHealth to cover any additional treatments or, if MassHealth had done so, that the treatments could not have been approved absent the MassHealth order expanding coverage.

62. The sentencing court did not require Dr. Baxter to pay restitution, nor had the Department of Justice suggested that any was warranted. Indeed, Dr. Baxter's presentencing report did not identify any "victims" associate with his RCO misdemeanor misbranding offense.

63. Simply put, the record supporting Dr. Baxter's conviction confirms that Dr. Baxter's offense was not "related to the delivery of an item or service under" a federal healthcare program for purposes Section 1128(a). The DAB's contrary determination was thus arbitrary, capricious, and contrary to law.

64. Finally, the DAB attempted to excuse an egregious claim by the ALJ that the APA's "arbitrary and capricious standard of review" did not apply to "administrative appeals of IG exclusions." As the DAB explained in response to Dr. Baxter's challenge, the standard for judicial review is "fundamentally different" than the standard for agency review. While that characterization may be debatable, the DAB refused to address the obvious question raised by Dr. Baxter: whether the IG's actions had, in fact, been arbitrary and capricious. In doing so, the DAB confirmed its willingness to affirm a decision without regard to whether the agency's reasoning in support was defensible.

65. On September 30, 2022, the DAB issued its ruling, making it the final decision of the Secretary. Dr. Baxter was therefore forced to challenge his exclusion with this Court.

COUNT I
Agency Action was Not in Accordance with Law

66. Paragraphs 1 through 65 are incorporated by reference as if fully restated herein.

67. The APA prohibits defendants from enforcing the Social Security Act in a manner that is contrary to law. *See* 5 U.S.C. § 706(2)(A).

68. Section 1128(a) of the Social Security Act enumerates limited circumstances in which the Secretary *must* exclude individuals from participation in Federal healthcare programs. 42 U.S.C. § 1320a-7(a). By contrast, the Secretary *may* exclude an individual for less serious offenses identified in Section 1128(b). 42 U.S.C. § 1320a-7(b). Convictions identified by the statute as qualifying for permissive exclusion necessarily cannot also qualify for mandatory exclusion.

69. If Dr. Baxter's conviction fits anywhere within this scheme, it is as "a misdemeanor relating to fraud" potentially subject to permissive exclusion. 42 U.S.C. 1320a–7(b)(1)(A).

70. The Secretary has previously interpreted the Social Security Act to mean that convictions for misdemeanor misbranding, 21 U.S.C. § 331(a) and § 333(a)(1), under the RCO doctrine, are subject to permissive exclusion where a Medicaid program purchases the misbranded drug. According to the Secretary, a conviction under these circumstances is "a misdemeanor relating to fraud." 42 U.S.C. 1320a–7(b)(1)(A); *see Friedman*, 686 F.3d at 816. In persuading the D.C. Circuit to endorse that interpretation, the Secretary explained that this has been the agency's "longstanding interpretation" of the statute. Brief for Appellee at 12, *Friedman v. Sebelius*, No. 11-5028 (D.C. Cir. Oct. 5, 2011).

71. Because permissive and mandatory exclusion are mutually exclusive, the Secretary cannot impose *mandatory* exclusion on the basis that Dr. Baxter's conviction for misdemeanor misbranding, 21 U.S.C. § 331(a) and § 333(a)(1), is also "a criminal offense related to the delivery of an item or service under subchapter XVIII," 42 U.S.C. § 1320a-7(a)(1).

72. Moreover, the circumstances of Dr. Baxter's conviction do not justify imposing

mandatory exclusion under Section 1128(a). The Secretary cannot demonstrate that Dr. Baxter's conviction was "related to the delivery of an item or service under subchapter XVIII," 42 U.S.C. § 1320a-7(a)(1), because the government never established that the misbranding was "related to" the delivery of Suboxone Film under MassHealth.

73. The Secretary's mandatory exclusion of Dr. Baxter was therefore contrary to law.

COUNT II
Agency Action was Arbitrary and Capricious

74. Paragraphs 1 through 73 are incorporated by reference as if fully restated herein.

75. The APA prohibits defendants from implementing the Social Security Act in a manner that is arbitrary and capricious, an abuse of discretion, or unsupported by substantial evidence. *See* 5 U.S.C. § 706(2)(A). The APA's arbitrary and capricious standard governs this Court's review of the Secretary's decision to impose mandatory exclusion on Dr. Baxter.

76. Agency action is arbitrary and capricious when it is unsupported by reasoned decision-making. In reaching a decision, an agency may not treat like individuals differently without providing adequate justification for doing so.

77. The Secretary has previously interpreted the Social Security Act to impose permissive exclusions on individuals convicted of misdemeanor misbranding under similar circumstances. Dr. Baxter's offense was materially indistinguishable from those committed by individuals against whom the Secretary chose to impose permissive exclusions.

78. The Secretary did not acknowledge his changed interpretation of the Act. Nor did he provide an adequate justification to depart from past practice in imposing a mandatory exclusion on Dr. Baxter for his conviction for misdemeanor misbranding.

79. The Secretary's mandatory exclusion of Dr. Baxter was therefore arbitrary and capricious.

COUNT III
Agency Action Violated Dr. Baxter's Fifth Amendment Right to Due Process of Law

80. Paragraphs 1 through 79 are incorporated by reference as if fully restated herein.

81. Dr. Baxter has a liberty interest in pursuing his chosen occupation as a physician that is protected by the Fifth Amendment's Due Process Clause.

82. The Secretary imposed a mandatory exclusion on Dr. Baxter solely on the basis of his misdemeanor conviction for a strict-liability offense. The government has never established that Dr. Baxter had any intent to commit a crime. "[D]ue process places some limits" on the government's ability to impose such a severe penalty on Dr. Baxter for his strict liability offense. *Lambert*, 355 U.S. at 228.

83. The mandatory exclusion imposed by the Secretary would deprive Dr. Baxter of his liberty interest without any rational connection to a legitimate government objective.

PRAYER FOR RELIEF

WHEREFORE, Dr. Baxter prays for a judgment in his favor and against the Secretary on his claim, granting Dr. Baxter the following relief:

A. An order setting aside Dr. Baxter's exclusion and declaring that the agency's decision was contrary to law, arbitrary and capricious, an abuse of discretion, and unsupported by substantial evidence, or, in the alternative, that Dr. Baxter's exclusion was a violation of the Due Process Clause of the Fifth Amendment;

B. An order awarding Dr. Baxter costs and attorneys' fees pursuant to 28 U.S.C. § 2412; and

C. Any other relief this Court deems just and proper.

Date: November 22, 2022

By: /s Brandon J. Moss
Thomas M. Johnson, Jr. (*pro hac vice* forthcoming)
Brandon J. Moss
Jeremy J. Broggi (*pro hac vice* forthcoming)
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CERTIFICATE OF SERVICE

I certify that on November 22, 2022, I caused a copy of the foregoing to be served on the following:

- The U.S. Attorney's Office for the Eastern District of Virginia, by certified mail to:

  Civil Process Clerk
  Office of the United States Attorney for the Eastern District of Virginia
  2100 Jamieson Ave
  Alexandria, VA 22314

- The Attorney General of the United States at Washington, D.C., by certified mail to:

  Jolene Ann Lauria
  Acting Assistant Attorney General for Administration[5]
  United States Department of Justice
  Justice Management Division
  950 Pennsylvania Avenue, NW
  Room 1111
  Washington, DC 20530

- Xavier Becerra, Secretary of the United States Department of Health and Human Services, by certified mail to

  U.S. Department of Health and Human Services
  Hubert H. Humphrey Building
  200 Independence Avenue, SW
  Washington, D.C. 20201

- Christi A. Grimm, Acting Inspector General of the United States Department of Health and Human Services, by certified mail to:

  Office of Inspector General
  U.S. Department of Health and Human Services
  330 Independence Avenue, SW
  Washington, DC 20201

/s Brandon J. Moss
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[5] Designated to accept service on behalf of the Attorney General by 28 C.F.R. § 0.77(j).